

MAY - 2 2008

Gyrus ACMI PKS Plasma Morcellator
Gyrus ACMI, Inc.
136 Turnpike Road
Southborough, MA 01772

Traditional 510(k) Notification
510(k) Summary
January 11, 2008

K080093

510(k) Summary of Safety and Effectiveness
Gyrus ACMI, Inc.
Gyrus ACMI PKS Plasma Morcellator

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General Information

Manufacturer: Gyrus Medical Ltd.
Fortran Road, St. Mellons
Cardiff UNITED KINGDOM CF3 0LT

Establishment Registration Number: 9617070

510(k) Submitter: Gyrus ACMI, Inc.
136 Turnpike Rd.
Southborough, MA 01772-2104

Establishment Registration Number: 3003790304

Contact Person: Terrence E. Sullivan
Vice President, Regulatory Affairs

Date Prepared: January 11, 2008

Device Description

Classification Name: Laparoscope, Gynecologic and
accessories (21 CFR 884.1720), Class II,
Obstetrics/Gynecology Panel;
Electrosurgical cutting and coagulation
device and accessories
(21 CFR 878.4400), Class II
General and Plastic Surgery Panel

Project Name: Gyrus Medical Solid Organ Resection
Device (SORD)

Trade Name: Gyrus ACMI PKS Plasma Morcellator

Generic/Common Name: Electrosurgical Instruments

Predicate Devices

Gyrus Medical Inc. PlasmaCision Laparoscopic Spatula	K041633
Ethicon Inc. Gynecare Laparoscopic Morcellator	K993801

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Intended Uses

The Gyrus ACMI PKS Plasma Morcellator is intended for cutting, coring, and extracting tissue in various operative laparoscopy procedures, including laparoscopic general surgical procedures, laparoscopic urological procedures, and laparoscopic gynecologic procedures.

Product Description

The Gyrus ACMI PKS Plasma Morcellator consists of two main elements: a Morcellator that includes a cutting shaft and handle with an integrated electrical cable that connects to a Gyrus Medical generator; and a Grasper that passes through the hollow shaft of the Morcellator, to grasp tissue and retract it toward the cutting element on the Morcellator shaft tip. An obturator may also be used to assist in the introduction of the device in laparoscopic procedures, and like the grasper, is positioned through the shaft of the Morcellator tube when being utilized.

Technological Characteristics and Substantial Equivalence

The Gyrus ACMI PKS Plasma Morcellator utilizes features incorporated into the following legally marketed predicate devices:

The Gyrus ACMI PKS Plasma Morcellator utilizes the same bipolar electrosurgical energy to cut tissue as that used in the predicate Gyrus Medical Inc. PlasmaCision Laparoscopic Spatula.

The Gyrus ACMI PKS Plasma Morcellator connects to the same electrosurgical generators, the currently marketed Gyrus PlasmaKinetic SuperPulse System and Gyrus General Purpose Electrosurgical System generators, as the predicate Gyrus Medical Inc. PlasmaCision Laparoscopic Spatula. These generators were cleared under K031085 and K050550, respectively.

The Gyrus ACMI PKS Plasma Morcellator is dimensionally similar to the predicate Ethicon Gynecare Laparoscopic Morcellator, having similar Morcellator shaft diameters.

Like the predicate Ethicon Gynecare Laparoscopic Morcellator, the Gyrus ACMI PKS Plasma Morcellator utilizes a pistol grip Morcellator with a hollow shaft through which a grasper is passed to grasp tissue to be resected.

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Like the predicate Ethicon Gynecare Laparoscopic Morcellator, the Gyrus ACMI PKS Plasma Morcellator is indicated for cutting, coring, and extracting tissue in various operative laparoscopy procedures, including laparoscopic general surgical procedures, laparoscopic urological procedures, and laparoscopic gynecologic procedures.

The Gyrus ACMI PKS Plasma Morcellator uses patient-contacting materials that are utilized in the predicate devices, as well as other legally marketed devices manufactured by Gyrus ACMI.

During design verification, the performance of the PKS Plasma Morcellator was compared against the known performance characteristics of the predicate Gynecare Laparoscopic Morcellator using the bipolar tissue cutting technology of the predicate Gyrus PlasmaCision Laparoscopic Spatula. Testing demonstrated that the performance requirements were met, and that the PKS Plasma Morcellator exhibited comparable performance characteristics to both the predicate care Laparoscopic Morcellator and predicate Gyrus PlasmaCision Laparoscopic Spatula.

In summary, the Gyrus ACMI PKS Plasma Morcellator is substantially equivalent to the predicate devices and presents no new questions of safety or efficacy.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 2 2008

Gyrus ACMI, Inc.
% Mr. Terrence E. Sullivan
VP, Regulatory Affairs
136 Turnpike Road
Southborough, Massachusetts 01772

Re: K080093

Trade/Device Name: Gyrus ACMI PKS Plasma Morcellator
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI, HET
Dated: April 17, 2008
Received: April 18, 2008

Dear Mr. Sullivan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson", with a stylized flourish at the end.

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Gyrus ACMI PKS Plasma Morcellator
Gyrus ACMI, Inc.
136 Turnpike Road
Southborough, MA 01772

Traditional 510(k) Notification
Statement of Intended Use
January 11, 2008

Device Name: Gyrus ACMI PKS Plasma Morcellator

510(k) Number: K 080093

Statement of Intended use:

The Gyrus ACMI PKS Plasma Morcellator is intended for cutting, coring, and extracting tissue in various operative laparoscopy procedures, including laparoscopic general surgical procedures, laparoscopic urological procedures, and laparoscopic gynecologic procedures.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: ☒ X ☐ OR Over-the-Counter Use: ☐

(Per 21 CFR 801.109)



(Division Sign-Off)

Division of General, Restorative,
and Neurological Devices

510(k) Number K080093